

STEP THERAPY POLICY

- POLICY:** Topical Agents for Atopic Dermatitis Step Therapy Policy
- Elidel[®] (pimecrolimus 1% cream – Bausch Health/Valeant, generic)
 - Eucrisa[®] (crisaborole 2% ointment – Pfizer)
 - Protopic[®] (tacrolimus 0.03% and 0.1% ointment – LEO, generic)

REVIEW DATE: 12/14/2022

OVERVIEW

Tacrolimus ointment and pimecrolimus cream are topical calcineurin inhibitors that are indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of **atopic dermatitis** in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.^{1,2} Tacrolimus ointment is indicated for moderate to severe atopic dermatitis while pimecrolimus cream is indicated for mild to moderate atopic dermatitis. Eucrisa, a phosphodiesterase 4 inhibitor, is indicated for the topical treatment of mild to moderate **atopic dermatitis**.

Tacrolimus 0.03% ointment and pimecrolimus cream are indicated for use in adults and children ≥ 2 years of age. Although there are data documenting the tacrolimus 0.1% strength's safety and efficacy in children, this product is not approved for use in pediatric patients. Neither tacrolimus 0.03% ointment nor pimecrolimus cream are indicated for use in children < 2 years of age; however, both agents have been studied in this patient population.³ Eucrisa is indicated for use in patients ≥ 3 months of age.³

Topical corticosteroids are generally indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.⁴

Guidelines

The Joint Task Force Atopic Dermatitis Practice Parameter (2012) and the American Academy of Dermatology Guidelines of Care for the Management of Atopic Dermatitis (2014) make similar recommendations with regard to the topical treatment of atopic dermatitis.^{5,6} In general, the topical calcineurin inhibitors are recommended for atopic dermatitis that is unresponsive to topical corticosteroids. Unlike the topical corticosteroids, the topical calcineurin inhibitors are not atrophogenic, so their use is also recommended in patients who are treating areas in which topical corticosteroid use would be inappropriate due to safety concerns (i.e., face, eyelids, genitalia, or skin folds). Neither set of guidelines addresses Eucrisa; however, it has not been found to be atrophogenic.⁴⁻⁶

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: prescription topical corticosteroids (brand or generic)

Step 2: generic pimecrolimus 1% cream, Elidel, Eucrisa, generic tacrolimus ointment (0.03% and 0.1% strengths), Protopic

CRITERIA

1. If the patient has tried a Step 1 Product, approve a Step 2 Product.
2. If the patient has a dermatologic condition on or around the face, eyes/eyelids, axilla, or genitalia, approve a Step 2 Product.
3. If the patient is < 2 years of age, approve Eucrisa.
4. No other exceptions are recommended.

REFERENCES

1. Elidel[®] cream [prescribing information]. Bridgewater, NJ: Bausch/Valeant; September 2020.
2. Protopic[®] ointment [prescribing information]. Madison, NJ: LEO; February 2019.
3. Eucrisa[®] ointment [prescribing information]. New York, NY: Pfizer; March 2020.
4. Triamcinolone acetonide cream [prescribing information]. Bronx, NY: Perrigo; September 2021.
5. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol.* 2013;131:295-299.
6. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. Section 2: management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71(1):116-132.